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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,238	12/29/2006	Arthur Zwingenberger	70566-0021US	5112

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EXAMINER	
MCADAMS, BRAD	

ART UNIT	PAPER NUMBER
2456	

MAIL DATE	DELIVERY MODE
12/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,238	ZWINGENBERGER ET AL.	
	Examiner	Art Unit	
	ROBERT B. MCADAMS	2456	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed on September 14, 2009.

2. Claims 12-14 and 18-20 are pending.

Response to Amendment

3. The amendment filed 09/14/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Paragraph 0041 introduces: "A seal 73 having a lifetime extending over a plurality of cycles of the cassette is placed between the lid 70 and the bottom 72 to tightly close the cassette". Although it is obvious to one of ordinary skill in the art to further define said seal as tightly closing a cassette between the lid and the bottom, a seal having a lifetime extended over a plurality of cycles of a cassette is new and not disclosed in the original disclosure. The original disclosure, paragraph 0042, only defines a tag indicating the number of cycles that it has been subjected to within its lifetime but not said seal.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-14 and 18-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed towards non-statutory subject matter.

As to **Claims 12-14 and 18-20,** a combination including an "RFID tag" is claimed. However said RFID tag is described in the specification, paragraph 11, as a “tag” which records data from an RF writer. Therefore, said tag could embody non-statutory subject matter such as a carrier wave, and is rejected under 35 U.S.C. 101.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **Claims 12-14 and 18-19** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended Independent Claim 12 includes new matter, “to tightly close said container. . . and said seal has a lifetime of a plurality of cycles of said container” which was newly amended to the specification paragraph 0041 as new subject matter not previously taught in the original disclosure.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claim 18** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 is dependent on cancelled Claim 17. Appropriate correction is required. For the purposes of examination, the Examiner will read Claim 18 as being dependent on Claim 12.

9. **Claim 12,** The term "tightly" is a relative term which renders the claim indefinite. The term "tightly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Furthermore, it is unclear which statutory category of invention the claimed "combination" falls into. Appropriate correction is required.

Response to Arguments

10. Applicant's arguments with respect to Claim 12 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. **Claims 12-14 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Veitch* (PCT Pub No. WO01/94016) in view of *Ng* (U.S. PGPub. No. 2003/0011474).

As to **Claim 12,** *Veitch* discloses an RFID tag configured to receive, record, store and make available for subsequent electronic transmission information relating to an instrument to be sterilized **(Sample containers 310 have an RFID tag which receive, record, store and make available information relating to the sample. Paragraph bridging Page 12 and 13).**

However, *Veitch* does not expressly disclose a seal to tightly close said container, wherein said tag is in said seal and said seal has a lifetime of a plurality of cycles of said container.

Ng, in the same field of endeavor, discloses a seal of a container to tightly close said container wherein said tag is in said seal **(Electronic Seal 32 contains Bolt 36 which tightly seals and locks a container door. Figure 2; Paragraph 0030)**.

Although *Ng* does not expressly disclose wherein the seal has a lifetime of a plurality of cycles of said container, it would have been obvious to a person of ordinary skill in the art since the purpose of *Ng's* seal is detect tampering of the container, therefore said seal would last a plurality of cycles of said container.

At the time of invention, it would have been obvious to a person of ordinary skill in the art to have combined the sterilization container as taught by *Veitch* with the RFID

being imbedded in the seal as taught by *Ng*. The motivation would have been to be able to count the amount of uses of the container.

As to **Claim 13,** *Veitch-Ng* further discloses wherein said information comprises the serial number of said container **(*Veitch;* Page 11, Lines 11-14).**

As to **Claim 14,** *Veitch-Ng* further discloses a combination with said container for a plurality of said instruments **(*Veitch;* RFID tag 420 is attached to sample container 410 holding samples in each container. Page 13, Lines 15-19).**

As to **Claim 19,** *Veitch-Ng* further discloses a tag in combination with an Autoclave for sensing and indicating a sterilization process to which an instrument has been subjected comprising: a power supply, a switch for determining when a predetermined temperature and/or pressure condition has been reached and for activating said power supply in response thereto, a sensor for detecting sterilization temperature and/or pressure conditions at a contact point, and a central processing unit for processing the information from the sensors and writing said information to said RFID tag for subsequent retrieval **(*Veitch;* Page 4, Lines 21-30)**.

13. **Claims 18 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Veitch* (PCT Pub No. WO01/94016) in view of *Ng* (U.S. PGPub. No. 2003/0011474) and in further view of *Teller* (U.S. Patent No. 6,454,162 B1).

As to **Claim 18,** *Veitch-Ng* disclose the tag as substantially discussed in Claim 12.

However, *Veitch-Ng* do not expressly disclose wherein the tag accumulates the number of sterilization procedures.

Teller, in the same field of endeavor, teaches wherein said tag is capable of accumulating the number of sterilizing procedures in which said seal has been used **(Column 2, Lines 51-65 and paragraph bridging Columns 2 and 3).**

At the time of invention, it would have been obvious to a person of ordinary skill in the art to embed the tag in the seal, as taught by *Veitch-Ng,* to accumulate the number of procedures performed as taught by *Teller*. The motivation would have been to assure proper procedure.

As to **Claim 20,** *Veitch* discloses a method of sealing a sterilizing cassette and for monitoring the contents of the cassette comprising the steps of:

providing a sterilizing cassette having a tray portion and a lid portion, said cassette being configured to receive a seal between said tray portion and said lid portion, placing a seal in said cassette between said tray portion and said lid portion **(Figure 1b),**

However, *Veitch* does not expressly disclose wherein said seal includes an RFID tag capable of recording the content of said cassette and the number of cycles to which the cassette has be subjected.

Ng, in the same field of endeavor, discloses a seal wherein said tag is in said seal **(Electronic Seal 32 contains Bolt 36 which tightly seals and locks a container door. Figure 2; Paragraph 0030)**.

Teller, in the same field of endeavor, discloses wherein said tag is capable of accumulating the number of cycles and contents in which the cassette has been used **(Column 2, Lines 51-65 and paragraph bridging Columns 2 and 3).**

At the time of invention, it would have been obvious to a person of ordinary skill in the art to embed the tag in the seal, as taught by *Veitch-Ng,* to accumulate the number of cycles performed as taught by *Teller*. The motivation would have been to assure proper procedure.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT B. MCADAMS whose telephone number is (571)270-3309. The examiner can normally be reached on Monday-Thursday 6:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bunjob Jaroenchonwanit can be reached on 571-272-3913. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. B. M./
Examiner, Art Unit 2456

/Bunjob Jaroenchonwanit/
Supervisory Patent Examiner, Art Unit 2456